## Food and Drug Administration, HHS

- (1) The label of the additive or of a mixture containing the additive shall bear:
  - (i) The name of the additive.
- (ii) A statement of the concentration of the additive in any mixture.
- (2) If in a retail package intended for household use, the label and labeling of the additive, or of a mixture containing the additive, shall bear adequate directions for use to provide a final food product which complies with the limitations prescribed in paragraph (a) of this section.
- (3) If in a retail package intended for household use, the label of the additive, or of a mixture containing the additive, shall bear the statement "Keep out of the reach of children".

# § 172.177 Sodium nitrite used in processing smoked chub.

The food additive sodium nitrite may be safely used in combination with salt (NaCl) to aid in inhibiting the outgrowth and toxin formation from *Clostridium botulinum* type E in the commercial processing of smoked chub in accordance with the following prescribed conditions:

- (a) All fish in smoking establishments shall be clean and wholesome and shall be expeditiously processed, packed, and stored under adequate sanitary conditions in accordance with good manufacturing practice.
- (b) The brining procedure is controlled in such a manner that the water phase portion of the edible portion of the finished smoked product has a salt (NaCl) content of not less than 3.5 percent, as measured in the loin muscle, and the sodium nitrite content of the edible portion of the finished smoked product is not less than 100 parts per million and not greater than 200 parts per million, as measured in the loin muscle.
- (c) Smoked chub shall be heated by a controlled heat process which provides a monitoring system positioned in as many strategic locations in the smokehouse as necessary to assure a continuous temperature throughout each fish of at least 160 °F for a minimum of 30 minutes.
- (d) The finished product shall be cooled to a temperature of 50  $^{\circ}F$  or below within 3 hours after smoking and

further cooled to a temperature of 38 °F or below within 12 hours after smoking. A temperature of 38 °F or below shall be maintained during all subsequent storage and distribution. All shipping containers, retail packages, and shipping records shall indicate with appropriate notice the perishable nature of the product and specify that the product shall be held under refrigeration (38 °F or below) until consumed.

- (e) To assure safe use of the additive:
- (1) The label and labeling of the additive container shall bear, in addition to the other information required by the Act, the name of the additive.
- (2) The label or labeling of the additive container shall bear adequate directions to assure use in compliance with the provisions of this section.

### § 172.180 Stannous chloride.

The food additive stannous chloride may be safely used for color retention in asparagus packed in glass, with lids lined with an inert material, in an amount not to exceed 20 parts per million calculated as tin (Sn).

## § 172.185 TBHQ.

The food additive TBHQ, which is the chemical 2-(1,1-dimethylethyl)-1,4-benz-enediol (Chemical Abstracts Service Registry Number 1948-33-0), also known as tertiary butylhydroquinone, may be safely used in food in accordance with the following prescribed conditions:

- (a) The food additive has a melting point of 126.5 °C-128.5 °C.
- (b) It is used as an antioxidant alone or in combination with BHA and/or BHT.
- (c) The total antioxidant content of a food containing the additive will not exceed 0.02 percent of the oil or fat content of the food, including the essential (volatile) oil content of the food.

## § 172.190 THBP.

The food additive THBP (2,4,5-trihydroxybutyrophenone) may be safely used in food in accordance with the following prescribed conditions:

- (a) The food additive has a melting point of 149 °C–153 °C.
- (b) It is used as an antioxidant alone or in combination with other permitted antioxidants.

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(c) The total antioxidant content of a food containing the additive will not exceed 0.02 percent of the oil or fat content of the food, including the essential (volatile) oil content of the food.

## Subpart C—Coatings, Films and **Related Substances**

#### §172.210 Coatings on fresh citrus fruit.

Coatings may be applied to fresh citrus fruit for protection of the fruit in accordance with the following conditions:

- (a) The coating is applied in the minimum amount required to accomplish the intended effect.
- (b) The coating may be formulated from the following components, each used in the minimum quantity required to accomplish the intended effect:
- (1) Substances generally recognized as safe for the purpose or previously sanctioned for the purpose.
  - (2) One or more of the following:

Component	Limitations
Fatty acids	Complying with § 172.860.
Oleic acid derived from tall oil fatty acids	Complying with § 172.862.
Partially hydrogenated rosin	Catalytically hydrogenated to a maximum refractive index of 1.5012 at 100 °C. Color of WG or paler.
Pentaerythritol ester of maleic anhydride-modi-	Acid number of 134-145; drop-softening point of 127 °C-173 °C; saponifica-
fied wood rosin .	tion number of less than 280; and a color of M or paler.
Do	Acid number of 176-186; drop-softening point of 110 °C-118 °C; saponifica-
	tion number of less than 280; and a color of M or paler.
Polyethylene glycol	Complying with § 172.820. As a defoamer and dispersing adjuvant.
Polyhydric alcohol diesters of oxidatively refined (Gersthofen process) montan wax acids .	Complying with §178.3770 of this chapter and having a dropping point of 77 to 83 °C (170.6 to 181.4 °F), as determined by ASTM Method D566–76 (Reapproved 1982), "Standard Test Method for Dropping Point of Lubri-
	cating Grease," which is incorporated by reference (copies are available
	from the American Society for Testing and Materials, 1916 Race St., Phila-
	delphia, PA 19103, or available for inspection at the Office of the Federal
	Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408)
	using as a solvent xylene-ethyl alcohol in a 2:1 ratio instead of toluene-
	ethyl alcohol in a 2:1 ratio.
Sodium lauryl sulfate	Complying with § 172.822. As a film former.
Wood rosin	Color of K or paler.

paragraph (b) (2) and (4) of this section, more of the listed adjuvants.

(3) In lieu of the components listed in the following copolymer and one or

Component	Limitations
Vinyl chloride-vinylidene chloride copolymer	As an aqueous dispersion containing a minimum of 75 percent water when applied.
Polyethylene glycol	As an adjuvant.  Do.  Do.

(4) In lieu of the components listed in the following rosin derivative and eiparagraph (b) (2) and (3) of this section, ther or both of the listed adjuvants:

Component	Limitations
Calcium salt of partially dimerized rosin	Having a maximum drop-softening point of 197 °C and a color of H or paler. It is prepared by reaction with not more than 7 parts hydrated lime per 100 parts of partially dimerized rosin. The partially dimerized rosin is rosin that has been dimerized by sulfuric acid catalyst to a drop-softening point of 95 °C to 105 °C and a color of WG or paler.
Petroleum naphtha	As adjuvant. Complying with § 172.250. As adjuvant.

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